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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/500,040

06/23/2004

Hans-Michael Eggenweiler

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7590

03/02/2007

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.

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EXAMINER

MOORE, SUSANNA

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

03/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/500,040

Applicant(s)

EGGENWEILER ET AL.

Examiner

Susanna Moore

Art Unit

1624

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 February 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See memo. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: 9, 13, 14, 22-30.
Claim(s) objected to: _____.
Claim(s) rejected: 31-33.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See memo.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

DETAILED ACTION

Applicants proposed amendment claim 31 would narrow the subject matter being claimed but it is not clear what is being claimed. The claim is drawn to a "method for treating a disease or disorder caused by the PDE VII isozyme in its role in regulating the activation and degranulation of human eosinophils." It is unclear as to what diseases are caused by PDE VII in this role versus diseases that are caused by PDE VII in some other role. Entering this would thus require a new 112, second paragraph rejection, which is a new issue. Thus, the amendments will not be entered.

The two Wands analysis rejections made for claims 32 and 33 will be addressed as one since Applicant has only provided one argument for both rejections.

Applicant's arguments regarding the enablement rejection of claims 32 and 33 have been fully considered but they are not persuasive. On page 18 of Applicant's Remarks, Applicant cites In re Marzocchi et. al., stating,

".. a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein...it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." (emphasis original).

This is an enablement rejection. The Examiner is not necessarily saying that the invention does not work just that undue experimentation will be required to make it work.

Applicant state on page 19, the fourth and fifth line from the bottom of the page, "Further, absolute predictability is not required" under the nature of the invention and predictability in the art. The Examiner did not say "absolute predictability" was required, only that physiological activity is unpredictable.

On page 20, lines 1-8, Applicants point out the Specification provides "significant guidance" on the compounds activity, the preparation of the compounds and formulations, modes of administration and particular applications. Also, Applicants believe it is routine experimentation to determine the dosage and administration regime. However, it is not routine for a vast range of largely different disorders to have the same dosage range.

In the State of Art section of the Wands analysis, Applicants state on page 20, "The fact that the art fails to teach or suggest applicants' compounds as having such activity or for use in such treatment methods is part and parcel for why it is a patentable invention." The Examiner is not pointing to the fact that the compounds are novel, but rather that there are no even similar compounds to rely on. Applicants go on to state, "As for the articles about unpredictability in being able to generally treat all cancers or other diseases, applicants respectfully submit that the claims are not as broad as alleged. The method claims are all directed to treating only those diseases or disorders caused by the PDE VII isozyme in its role in regulating the activation and degranulation of human eosinophils. One of ordinary skill in the art would be able to reasonably determine what diseases or disorders would fall within this recitation." Note, tumour growth covers nearly all forms of cancer, except leukemias, i.e. tumor growth covers all solid cancers.

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Claim 32 in effect, says tumour growth generally can be controlled by PDE VII inhibition, that tumour growth generally is in the category of disorders controllable by PDE VII inhibition.

Under Working Examples, Applicants state at the bottom of page 20, "Although the specification does not contain working examples of actual methods of treatment, the law is clear that it is not necessary to provide working examples in order to enable the invention. See, e.g., *In re Borkowski*, 422 F.2d 904, 164 USPQ 642 (CCPA 1970); and, *In re Angstadt*, 537 F.2d 498, 190 USPQ 214 (CCPA 1976)." The Examiner has not said working examples are required but that the lack of working examples is a factor considered under the Wands analysis.

Applicants arguments addressed to the Level of the Skill in the Art are not persuasive. Applicants have not dealt with the teachings of the *Castro et. al.* reference, which directly addresses the issue.

Under Quantity of Experimentation Applicants state on page 21, "Enablement is found even where there is a large amount of routine experimentation." However true, the experimental work to get a drug to treat acute or chronic heart failure generally would be far from routine. Acute and chronic heart failures occur from a variety of mechanisms, and there has, in fact, never been such a drug, nor is there any reason to think there ever will be.

Lastly, Applicants believe claim 32 is narrowed by the dependent claim 33. The Examiner disagrees since heart disease or restenosis is a broad category of unrelated diseases, which was discussed previously.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susanna Moore whose telephone number is (571) 272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Art Unit 1624
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